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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/753,313 | 12/29/2000 | Gerardo Castillo | PROTEO.P16 | 1184 |

7590 09/30/2004

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| EXAMINER | |
|---|---|
| TATE, CHRISTOPHER ROBIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/753,313 | CASTILLO ET AL. | |
| | Examiner | Art Unit | |
| | Christopher R. Tate | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *4,5,10-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) *11-13 and 15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's election of Group I, claims 4, 5, and 10 in the reply filed on July 7, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4, 5, and 10 are presented for examination on the merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui Norin (JP 10-245342), by Takami et al. (JP 10-175858), or by Castillo et al. (WO 98/51302).

A method of treating, inhibiting, or managing amyloid fibril formation, deposition, accumulation, aggregation, and/or persistence in Alzheimer's disease in a mammalian subject via administering a therapeutic amount of green tea, green tea extract, or epicatechin thereto is claimed.

Mitsui Norin teaches the administration (e.g., in oral dosage form) of a therapeutically effective amount of epicatechin, as well as green tea extract, to a subject suffering from Alzheimer's disease so as to inhibit senile plaque formation due to the deposition of beta-amyloid protein on brain nerve cells and, thus, reduce the toxicity of

beta-amyloid protein (which is medically well known to be responsible for amyloid fibril formation, deposition, accumulation, aggregation, and/or persistence). See entire English translation of this JP patent.

Takami et al. teach the administration (e.g., in the form of a pharmaceutical tablet, capsule, etc; or within a consumable drink or food, etc) of a pharmacologically effective amount of a green tea extract (termed TEAFURAN 30) containing epicatechin therein, or a component thereof - such as epicatechin, including to someone suffering from Alzheimer's disease brought about by toxicity of beta amyloid protein (see discussion above with respect to such toxicity). See entire computer-generated English translation of the JP patent.

Castillo et al. teach the administration (e.g., in oral dosage form) of an effective amount of an *Uncaria tomentosa* extract containing naturally occurring polyphenols (which would inherently include epicatechin) for the instantly claimed purpose. See entire document.

As set forth in previous Office action, the above reference methods would inherently provide the functional effects instant claimed - i.e., would inherently treat, inhibit, or manage amyloid fibril formation, deposition, accumulation, aggregation, and/or persistence in a subject suffering from Alzheimer's disease upon such oral consumption.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsui Norin and Takami et al. (JP 10-175858), or over Castillo et al., in view of Chatterjee et al. (US 4,892,883) as well as the recognized state of the art.

The primary references are relied upon for the reasons discussed *supra*. None of these references expressly teach the further inclusion of the herbal agents instantly recited in claim 10.

Chatterjee et al. beneficially disclose that administration of *Ginkgo biloba* is useful in the therapy of Alzheimer's disease (see, e.g., col 7, lines 13-39). In addition, it is noted that none of the herbal agents recited in claim 10 were actually tested in the instant Examples, and page 6, lines 14-20 of the instant specification merely states that they are amyloid inhibitory ingredients. Accordingly, it appears that they are admittedly well known in the art to function as such.

It would have been obvious to employ a therapeutically effective amount of epicatechin, as well as green tea extract - such as beneficially taught by Mitsui Norin and Takami et al., for administering to a subject suffering from Alzheimer's disease so as to inhibit senile plaque formation due to the deposition of beta-amyloid protein on brain nerve cells, as well as to employ the polyphenol compositions taught by Castillo et al. (which would intrinsically contain naturally occurring epicatechin therein) for such

purpose, based upon the beneficial teachings provided therein. [As noted above and in previous Office actions, the reference methods would intrinsically provide the functional effects instant claimed - i.e., would intrinsically treat, inhibit, or manage amyloid fibril formation, deposition, accumulation, aggregation, and/or persistence in a subject suffering from Alzheimer's disease upon such oral consumption.]

It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine green tea extract and/or epicatechin with one or more of the herbal ingredients recited in claim 10 for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is beneficially taught and/or admittedly well known by the prior art to be useful for the same purpose (e.g., treating Alzheimer's disease) in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4, 5, and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-30 of copending Application No. 10/624,435 and over claims 24-30 of copending Application No. 10/624,436, in view of Chatterjee et al. (US 4,892,883) as well as the recognized state of the art.

With respect to instant claims 4-5, although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a method of treating or managing amyloidosis in a mammal via administering an effective amount of epicatechin (which is termed "fraction J" in the claim language of US '435 and '436) thereto. Accordingly, instant claims 4-5 are encompassed by the method of claims 24-30 of US Patent Application Nos. '435 and '436.

The claimed invention of US '435 and '436 do expressly teach the further inclusion of the herbal agents instantly recited in claim 10.

Chatterjee et al. beneficially disclose that administration of *Ginkgo biloba* is useful in the therapy of Alzheimer's disease (see, e.g., col 7, lines 13-39). In addition, it is noted that none of the herbal agents recited in claim 10 were actually tested in the instant Examples, and page 6, lines 14-20 of the instant specification merely states that they are amyloid inhibitory ingredients. Accordingly, it appears that they are admittedly well known in the art to function as such.

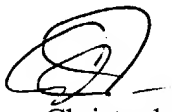
It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine epicatechin ("Fraction J") with one or more of the herbal ingredients recited in instant claim 10 for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is beneficially taught and/or admittedly well known by the prior art to be useful for the same purpose (e.g., treating Alzheimer's disease) in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654